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AUTHOR:	KINGA SVASTICS
APPROVING OFFICER:	PAMELA WARD
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Hungary has become the first country in Central and Eastern Europe to introduce medical device regulations that implement the European Union's Medical Device Directives (MDD). Decree 47/1999 on medical devices came into force in April 2000 and transposes the EU's MDD and Active Implantable Medical Device Directive (AIMDD). While the decree has a few, minor "national" features, all the annexes of the MDD and AIMDD, are simply translated into Hungarian thus can be referred easily to the original numbering.

Although Hungarian regulations are now in line with those of the EU, Hungary still operates as an independent market separate from the EU. There are some additional, temporary, local regulatory requirements until Hungary becomes a full-fledged EU member. For example, currently CE-marked devices tested by a Notified Body in the EU, must be reviewed by ORKI, the only Notified Body for medical products in the country in order to receive the necessary "H" marking. When Hungary joins the EU, the repeat testing will become redundant. According to the MDD, CE marking is accepted for Class I (low-risk) products that do not need testing by a Notified Body.

To ease the transition period, in July 2000 the Protocol for European Conformity Assessment (PECA) was initialed by Hungary and the EU. This "bridging instrument" is expected to enter into force some time in 2001. It is essentially a mutual recognition agreement whereby all EU member states and Hungary will accept testing/certification by each other's Notified Bodies. The Protocol covers medical devices (among other industry sectors). Manufacturers

from third countries, including the United States, must have their medical products (even CE-marked products) tested and certified by the relevant Hungarian Notified Body until Hungary joins the EU (expected by 2005). Manufacturers from the U.S. and othr third countries, which already have mutual recognition agreements with the EU, will not be able "to ride on the back of the PECA, according to Hungarian rules. The only exceptions will be products of U.S. firms manufactured in an EU country, the country of origin being determined based on the location of the manufacturing site. With PECA in place, if a U.S. medical device manufacturer has a plant in Germany and the products are CE-marked by the German Notified Body, no repeat certification/testing will be required.

While Decree 47/1999 institutes a number of changes, permits and certificates issued by ORKI prior to April 1, 2000 will be valid until the registered deadline. After April 1, 2000 new applications must conform to the new requirements of the law. Also under the new decree, ORKI the former "authority" became the Notified Body. Since April 2000 ORKI has no authority to issue permits, it acts "only"as all notified bodies worldwide: issues certificates as step 1 of product marketing.

The new authority is the Hungarian Authority for Medical Devices, which is affiliated with the Ministry of Health. The Authority maintains a national vigilance reporting system. In addition to registration, the Authority must be informed of identification data for Class I (sterile and/or measuring products), Class IIb and III (medium- and high-risk) devices as well as product labeling and instructions for products prior to initial market entry. Also Hungary has introduced a system for regular periodic testing of certain devices, which must be conducted by the end-users, clinics and hospitals and is controlled by the Authority for Medical Devices.

Under the Hungarian regulations, manufacturers must have an authorized representative in Hungary. This representative initiates the application process, provides necessary documentation, and decides upon which annex ORKI should perform the certification.

The new decree 47/1999 is available in "draft" translation with the Foreign Commercial Service in Budapest as is the "Preliminary Request Form for Conformity Assessment" with Guideline.

Key Contacts

Ministry of Welfare
Orvostechnikai Hivatal
(Hungarian Authority for Medical Devices)
Mr Laszlo Raduj, Director
Arany Janos u. 6/8
1051 Budapest, Hungary
Tel: (36 1) 332 3100 Fax:(36 1) 302 0925
Web site of the Ministry: www.eum.hu
(under Institutions: Orvostechnikai Hivatal)

Notified Body for Medical Devices and Active Implants is:
ORKI Institute for Medical and Hospital Engineering
Mr Csaba Nagy, Director General

Dios arok u. 3
1125 Budapest, Hungary
Tel: (36 1) 356 1522 Fax: (36 1) 375 7253
Web site: www.orki.hu
E-mail: orki@orki.hu

American Embassy, Commercial Service
Pamela Ward, Commercial Attache
E-mail: pamela.ward@mail.doc.gov
Ms Kinga Svastics, Commercial Specialist
E-mail: kinga.svastics@mail.doc.gov
Web site: www.usatrade.gov
Tel: (36 1) 475 4090 Fax: (36 1) 475 4676